FORM PTO-1390 (Modified) (REV 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: **15568.1**

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR): 10/009102

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB00/02137	**2 June 2000 (02.06.00)**	**4 June 1999 (04.06.99)**

TITLE OF INVENTION

SEALED ENCLOSURE STERILIZATION

APPLICANT(S) FOR DO/EO/US

WATLING, David

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include itens (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

    Postcard

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/009102	PCT/GB00/02137	15568.1

24. The following fees are submitted:.

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

		CALCULATIONS PTO USE ONLY
☐	Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	$1040.00
☒	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	$890.00
☐	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	$740.00
☐	International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)	$710.00
☐	International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)	$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT =	$890.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	$0.00	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	13 - 20 =	0	x $18.00	$0.00	
Independent claims	2 - 3 =	0	x $84.00	$0.00	
Multiple Dependent Claims **(check if applicable).**			☐	$0.00	

TOTAL OF ABOVE CALCULATIONS =	$890.00	
☐ Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.	$0.00	
SUBTOTAL =	$890.00	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +	$0.00	
TOTAL NATIONAL FEE =	$890.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).** ☐	$0.00	
TOTAL FEES ENCLOSED =	$890.00	
Amount to be: refunded	$	
charged	$	

a. ☐ A check in the amount of _____ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **23-3178** A duplicate copy of this sheet is enclosed.

d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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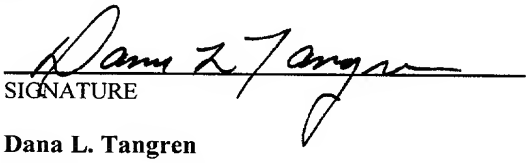

SIGNATURE

Dana L. Tangren
NAME

37,246
REGISTRATION NUMBER

December 4, 2001
DATE

Express Mail Label No. EL 814 017 285 US

PATENT APPLICATION
Docket No. 15568.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of		)
		)
Inventor:	David Watling	)
		)
International		)
Application Number:	PCT/GB00/02137	)
		)
U.S. Filing Date:		)
		)
For:	SEALED CLOSURE STERILIZATION	

PRELIMINARY AMENDMENT

Box PCT
Honorable Commissioner of Patents and Trademarks
P.O. Box 2327
Arlington, VA 22202

Sir:

Prior to calculating the filing fee for the above-identified patent application, please incorporate the following amendments:

IN THE SPECIFICATION

At the end of the application insert the following Abstract.

--ABSTRACT OF THE DISCLOSURE

An apparatus for sterilising a sealed enclosure (1) includes a fan (8) for circulating a gas through a preparation circuit (11) and through the enclosure. The preparation circuit includes an evaporation chamber (10) for dispensing a decontaminant gas and water vapour mixture into the circulating gas to flow therewith through the enclosure and to reach a concentration in the enclosure above the dew point for the ambient temperature in the enclosure and thereby to condense onto surfaces in the enclosure to sterilise such surfaces. A monitor (15) measures gas temperature and dew point/condensation are monitored (17, 18) in the enclosure. The resulting signals led to a control module (19) for controlling the rate of dispensing of the decontaminant gas and water vapour into the gas in the preparation circuit in response to the levels determined by said monitoring to provide a required level of condensation of the decontaminant gas and water vapour in the enclosure.

IN THE CLAIMS

Please cancel claims 1-12.

Please add the following new claims 13-25:

13. (New) A method of sterilising a sealed enclosure comprising: circulating a gas through the enclosure and through a preparation region, dispensing a mixture of decontaminant gas and water vapour into the circulating gas in the preparation region to flow therewith through the enclosure to reach a concentration in the enclosure above the dew point of the gas and water vapour mixture for the ambient temperature in the chamber and thereby to condense onto surfaces in the enclosure to sterilise such surfaces; wherein the gas temperature in or exiting the enclosure or entering the preparation region, decontaminant gas concentration in or exiting the enclosure or entering the preparation region and condensation of the decontaminant gas in the enclosure are monitored, and the dispensing of mixture of decontaminant gas and water vapour into the gas in the preparation region is controlled in response to the levels determined by said monitoring to provide a requisite level of condensation of the decontaminant gas/water vapour in the enclosure.

14. (New) A method of sterilising a sealed enclosure as claimed in claim 13, wherein the gas circulated through the enclosure is air.

15. (New) A method as claimed in claim 13, wherein the gas is filtered in said preparation region prior to circulation through the enclosure.

16. (New) A method as claimed in claim 14, wherein the gas is filtered in said preparation region prior to circulation through the enclosure.

17. (New) A method of sterilising a sealed enclosure as claimed in claim 13, wherein means are provided for monitoring the gas pressure in the enclosure and means are provided for adjusting the gas pressure therein by controlling the supply of gas circulating through the enclosure.

18. (New) A method as claimed in claim 13, wherein after a sufficient amount of decontaminant gas has been condensed in the chamber to achieve decontamination, supply of the decontaminant gas and water vapour mixture to the preparation region is terminated and the decontaminant gas is removed from the sealed enclosure.

19. (New) A method of sterilising a sealed enclosure as claimed in claim 18, wherein the method of moving the decontaminant gas from the sealed enclosure comprises:

passing clean filtered gas through the enclosure and releasing the gas exiting the enclosure to atmosphere; or

circulating the gas exiting the enclosure through an auxiliary circuit containing a catalytic decomposition device or absorption device for the decontaminant gas to remove the decontaminant gas.

20. (New) An apparatus for sterilising a sealed enclosure comprising means (8) for circulating a gas through a preparation region (3) and through the enclosure (1) means (10) in the preparation region for dispensing a mixture of decontaminant gas and water vapour mixture into the circulating gas to flow therewith through the enclosure to reach a concentration in the enclosure above the dew point for the ambient temperature in the chamber and thereby to condense onto surfaces in the enclosure to sterilise such surfaces wherein means (15) are provided for monitoring gas temperature in or exiting the enclosure or entering the preparation region, means (17, 18) are provided for monitoring the condensation of the decontaminant gas in or exiting the enclosure or entering the preparation region and said means (19) for controlling the dispensing of the mixture of decontaminant gas and water vapour into the gas in the preparation region are controlled in response to the levels determined by said monitoring to provide a predetermined level of condensation of the mixture of decontaminant gas and water vapour in the enclosure.

21. (New) An apparatus as claimed in claim 20, further comprising means for circulating air through the preparation region and enclosure to convey the decontaminant gas/water vapour mixture to the enclosure.

22. (New) An apparatus as claimed in claim 20, further comprising means for filtering the gas in said preparation region prior to circulation through the enclosure.

23. (New) An apparatus as claimed in 20, further comprising:

means for monitoring the gas pressure in the enclosure; and

means for adjusting the gas pressure therein by controlling the supply of gas circulating through the enclosure.

24. (New) An apparatus as claimed in claim 20, wherein the control means are arranged to terminate supply of the decontaminant gas and water vapour mixture in the preparation region after a sufficient amount of decontaminant gas has condensed in the enclosure to achieve decontamination and for removing the decontaminant gas from the enclosure.

25. (New) An apparatus as claimed in claim 24, wherein the means for removing the decontaminant gas from the sealed enclosure comprises means for passing clean filtered gas through the enclosure and releasing the gas exiting the enclosure to atmosphere, or means for circulating the gas exiting the enclosure through an auxiliary circuit containing a catalytic decomposition device or absorption device for the decontaminant gas to remove the decontaminant gas.

REMARKS

By this Preliminary Amendment, applicant has added an Abstract of the Disclosure. The added abstract is supported by the abstract of the International Application to which the present national application claims priority. As required, a copy of the abstract is also attached hereto on a separate sheet of paper. Claims 1-12 have been canceled while claims 13-25 have been added. New claims 13-25 are supported by original claims 1-12 and have simply been redraft to remove multiple

dependencies and to place the claim language in a more conventional format for U.S. prosecution. Applicant submits that the claim amendments are formal in nature and were not made with regard to patentability. For the foregoing reasons, applicant respectfully submits that the amendments to the specification and the claims do not introduce new matter, and entry thereof is respectfully requested.

In view of the forgoing, claims 13-25 are presented for the Examiner's consideration on the merits.

Dated this 4th day of December, 2001.

Respectfully submitted,

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SEALED ENCLOSURE STERILIZATION

The present invention relates to decontamination and sterilisation systems and more particularly to the control of gaseous decontamination and systems where the vapour has more than one component.

Conventional gas sterilisation and decontamination systems have been designed in order to avoid condensation, and as such both flow through and recirculating systems have been so organised as to keep the vapour concentrations, especially of water, below the dew point. Examples of such systems are described in European Patent EP0486623B1, UK Patent 2 217 619 B, WO 89/06140 and UK Patent application GB 2308 066 A.

More recent work has shown that for rapid surface sterilisation and decontamination in rooms and smaller chambers, or isolators, condensation of a mixture of vapours of a gaseous decontaminant such as hydrogen peroxide and water is essential.

The object of the present invention is to control the sterilisation and decontamination systems both for closed recirculating systems, flow through systems and systems which use recirculation with a proportion of the recirculation air or air/gas mixture being exhausted from the closed system so that condensation may occur rapidly, evenly and controllable through the area to be sterilised or decontaminated.

For the purpose of this patent the term decontaminate shall in future include both chemical and microbiological decontamination. Microbiological decontamination shall mean the reduction of the viable

bioburden, which is generally described either as sterilisation, sanitation or disinfection.

This invention provides a method of sterilizing a sealed enclosure comprising the steps of: circulating the gas through the enclosure, and through a preparation region, in the preparation region dispensing a decontaminant gas and water vapour mixture into the circulating gas to flow therewith through the enclosure to reach a concentration in the enclosure above the dew point for the ambient temperature in the chamber and thereby to condense onto surfaces in the enclosure to sterilise such surfaces; wherein the gas temperature and the condensation of the decontaminant gas in the enclosure are monitored and the dispensing of the decontaminant gas and water vapour into the gas in the preparation region is controlled in response to the levels determined by said monitoring to provide a requisite level of condensation of the decontaminant gas/water vapour in the enclosure.

The term "sealed enclosure" shall include any chamber or room that may for practical purposes be sealed so as to prevent the escape of such amounts of active gas as to cause a hazard.

The sealed enclosure is connected to a means of processing by two pipes through which air or a mixture of air and gases, where the gases are hydrogen peroxide and water vapour, may circulate. The air or mixture of air and gases being delivered from the means of processing to the sealed enclosure to then be returned to the processing means or alternatively a flow through system where the air or air/gas mixture is vented from the sealed enclosure in a safe manner. The air or mixture of air and gases on entering the means of processing may, if necessary, first pass through a

system of purification to remove and make safe any gases within the mixture of air and gases. This purification process will not normally be required because of the stability of the gas mixture. Hydrogen peroxide gas has been shown to be stable in the homogenous vapour phase at ambient and temperatures below 300°C. Decomposition will occur on surfaces but only at insignificant rates on those surfaces generally found in clean rooms and isolators. High rates of decomposition will occur on certain organic substances such as micro-organisms but as the quantity of these materials is very small the total amount of decomposition is also very small, and hence does not significantly affect the gas concentration. A fan or pump or compressor is then used to propel the air or mixture of air and gases around the system, and drive the fluid through the evaporation chamber where additional gases are added to the air or air gas mixture. The enriched air/gas mixture is then passed through the connection from the processing means to the sealed chamber.

The function of the air/gas mixture in the sealed chamber is to decontaminate the surfaces of the chamber.

Similar systems have been employed for some time for the surface sterilisation of sealed enclosures, but in these applications it has always been considered important to avoid condensation, Patent EP 0 486 623 B1 specifically sets out a table of operation to avoid condensation. The present invention sets out a method of decontamination by micro condensation and provides for a method of control. It has been established that faster and more reliable surface decontamination may be achieved if micro condensation is encouraged and controlled. The dew point of any hydrogen peroxide and water vapour mixture may be ascertained from the activity coefficients for the gases, and by using a

combination of dew point data, the actual dew point within the sealed chamber and the temperature it is possible to calculate the concentration of hydrogen peroxide in the condensate.

A knowledge of the condensation parameters, and the amount of condensation allows a prediction of the time at which surface decontamination will occur. For such a system to function reliably it is also essential that there is very good distribution of gas within the sealed enclosure.

The active gas in such micro-condensation systems used for decontamination is not limited to hydrogen peroxide but includes a gas or mixture of gases that exhibits the correct vapour pressure characteristics.

The invention also provides an apparatus for sterilizing a sealed enclosure comprising means for circulating a gas through a preparation region and through the enclosure and means in the preparation region for dispensing a decontaminant gas and water vapour mixture into the circulating gas to flow therewith through the enclosure to reach a concentration in the enclosure above the dew point for the ambient temperature in the chamber and thereby to condense onto surfaces in the enclosure to sterilise such surfaces; wherein means are provided for monitoring the temperature and the concentration of the decontaminant gas in the enclosure and means are provided for controlling the rate of dispensing of the decontaminant gas and water vapour into the gas in the preparation region in response to the levels determined by said monitoring to provide a predetermined rate of condensation of the decontaminant gas and water vapour in the enclosure.

The following is a description of one embodiment of the invention, reference being made to the accompanying drawing which is a diagrammatic illustration of a decontamination apparatus for a sealed enclosure.

The sealed enclosure 1 is connected to a sealed outlet pipe at 2 which connects to the processing means at 3. The air or air/gas mixture then passes through a filter 4 to remove particulate contamination. As an option if it is considered that the gas mixtures may have partially decomposed in the sealed chamber the air or air/gas mixture may be passed through a purification process 5. Step 5 is only required in exceptional circumstances when significant decomposition of the active gas has taken place. This component would not normally form part of the processing means. The air or air/gas mixture should then be heated in 7 to bring it to a stable temperature before passing to the fan or pump or compressor 8 which is used to drive the air or air/gas mixture through the processing means, the connecting pipes and the sealed enclosure. The volumetric flow is then measured in 9 before the air or air gas mixture is passed to the evaporation chamber 10 where more of the gas mixture is added by evaporation of the decontamination solution on a hot surface. The air or air /gas mixture passes through a filter 25 before entering the evaporation chamber 10 to ensure that particulate matter is removed from the flow. The rate at which the liquid is fed to the evaporation chamber 10 is controlled by the Liquid Flow Module 22.

Because it may be necessary to control the pressure inside the sealed enclosure a pressure control module 21 is used to raise or lower the pressure by supply or extracting air. Any air added to the system must be filtered 23 and any air extracted must be rendered safe by the removal of any active gas either by absorbing the

gas or by decomposition with a catalyst 24. The air or air/gas mixture leaves the processing means at 11 through a sealed connecting pipe and is delivered to the sealed enclosure at 12. Within the sealed enclosure is a gas distribution device 13 which generates sufficient turbulence in the air or air/gas mixture within the sealed enclosure to ensure rapid and even distribution of the air or air/gas mixture.

The gas distribution system in the simplest form would be a circulating fan mounted inside the sealed enclosure which generated sufficient turbulence in the air gas mixture to generate an even distribution of gas. A more affective technique would be to use a nozzle rotating about two axles at right angles directing a jet of gas as it is delivered to the chamber at high velocity over a fixed pattern. The use of such a rotating nozzle has the advantage of generating repeating patterns over the internal surface of the sealed chamber. It also allows the air/gas mixture to be delivered at an optimum temperature from a heated pipe 11 to 12 and by correct design of the nozzle allows the delivered gas velocity to be adjusted to suit the geometry of the chamber.

A pressure sensing point 14 on the sealed enclosure is connected by a sealed tube to the pressure sensing device at 16. The signal from the pressure sensor is transmitted to the control module 19 which in turn sends signals to the pressure control module 21 to adjust the internal pressure of the sealed enclosure. Such pressure control may be inactivated when it is not possible because of the size of construction of the sealed enclosure or when pressure control is not required. The dew point and condensation monitor 17 is connected electronically to the processing unit 18 which may be either attached to the sealed enclosure or in the processing means. The signal from the dew point and

condensation processing unit is passed to the control module and is used to control the rate of micro-condensation that occurs inside the sealed enclosure. The temperature 15 of the air or the air/gas mixture either inside the sealed enclosure, or leaving the sealed enclosure, or on entering the processing means is measured and the signal passed to the control module 19. A gas sensor 20 measures the gas concentration either inside the sealed enclosure, or on leaving the sealed enclosure, or on entering the processing means. The signal from the gas sensor is transmitted electronically to the control module 19. If the distance from the processing means to the sealed enclosure is great the pipe connecting 11 to 12 should be heated and insulated to maintain the temperature above the dew point of the air/gas mixture being delivered from the evaporation chamber.

Method of Control

As the decontamination process relies on micro-condensation on particles on the surface it is important that this process is controlled. This control is achieved with reference to the dew point and rate of condensation as measured on the dew point and condensation sensor 17 together with the temperature sensor 15 and the gas sensor 20.

After an initial stabilisation period during which the air flow and temperature are stabilised, the liquid flow module 22, under the direction of the control module 19 will start to dispense a measured flow of liquid to the evaporation chamber 10. This measure flow of liquid will be turned into a gas mixture in the evaporation chamber and mixed with a measured flow of air as measured by the flow measurement device 9 and controlled via the control module 19 by the fan or pump or

compressor 8.

This technique will provide a predetermined air gas mixture concentration which will be delivered to the sealed enclosure 1 and evenly distributed throughout the chamber by the distribution device 13. This air/gas mixture must have a concentration above the dew point for the temperature of the sealed enclosure 1. Once sufficient air/gas mixture has circulated round the system through the sealed enclosure and the processing means to raise the air/gas concentration above the dew point then the condensation will occur and be signalled by the dew point and condensation sensor 17. From a knowledge of the temperature as indicated by the temperature sensor 15 and the gas concentration as indicated by the gas sensor 20 and the dew point it is possible to derive the concentration of the sterilant in the micro-condensation. Once the dew point has been reached the rate of liquid delivered by the liquid flow module 22 to the evaporation chamber 10 will be adjusted to achieve the required rate of condensation in the sealed enclosure. After a sufficient amount of condensation has occurred as measured by the dew point and condensation sensor 17 and also by the amount of liquid delivered from the liquid flow module 22 to the evaporation chamber 10 then the liquid flow is stopped as decontamination will have been achieved. The amount of condensation in any sealed enclosure to achieve decontamination will have to be demonstrated by the use of a testing technique suitable for the containment.

Once the liquid flow from the liquid flow module 22 to the evaporation chamber 10 has been stopped then a system to remove the decontaminant gas from the sealed enclosure 1 must be operated. This may either consist of a method of passing clean filtered air through the sealed enclosure 1 and passing the air from the sealed

enclosure which will then contain active gas safely to atmosphere or by circulating the air/gas mixture through an auxiliary circuit to remove the decontaminant gas. Such an auxiliary circuit could be either a catalyst decomposition device or an absorption technique such as activated carbon. It may also be possible to use a combination of both methods, first reducing the concentration with a catalyst or activated carbon and then passing the balance safely to atmosphere.

CLAIMS

1. A method of sterilizing a sealed enclosure comprising the steps of: circulating the gas through the enclosure, and through a preparation region, in the preparation region dispensing a decontaminant gas and water vapour mixture into the circulating gas to flow therewith through the enclosure to reach a concentration in the enclosure above the dew point for the ambient temperature in the chamber and thereby to condense onto surfaces in the enclosure to sterilise such surfaces; wherein the gas temperature and the condensation of the decontaminant gas in the enclosure are monitored and the dispensing of the decontaminant gas and water vapour into the gas in the preparation region is controlled in response to the levels determined by said monitoring to provide a requisite level of condensation of the decontaminant gas/water vapour in the enclosure.

2. A method of sterilizing a sealed enclosure as claimed in claim 1, wherein the gas circulated through the enclosure is air.

3. A method as claimed in claim 1 or claim 2, wherein the gas is filtered in said preparation region prior to circulation through the enclosure.

4. A method of sterilizing a sealed enclosure as claimed in any of the preceding claims, wherein means are provided to monitor the gas pressure in the enclosure and means are provided to adjust the gas pressure therein by controlling the supply of gas circulating through the enclosure.

5. A method as claimed in any of the preceding claims, wherein after a sufficient amount of decontaminant gas has been condensed in the chamber to achieve

decontamination, supply of the decontaminant gas and water vapour mixture to the preparation region is terminated and the decontaminant gas is removed from the sealed enclosure.

6. A method of sterilizing a sealed enclosure as claimed in claim 5, wherein the method of removing the decontaminant gas from the sealed enclosure comprises the step of passing clean filtered gas through the enclosure and releasing the gas exiting the enclosure to atmosphere, or by circulating the gas exiting the enclosure through an auxiliary circuit containing a catalytic decomposition device or absorption device for the decontaminant gas to remove the decontaminant gas.

7. An apparatus for sterilizing a sealed enclosure comprising means for circulating a gas through a preparation region and through the enclosure and means in the preparation region for dispensing a decontaminant gas and water vapour mixture into the circulating gas to flow therewith through the enclosure to reach a concentration in the enclosure above the dew point for the ambient temperature in the chamber and thereby to condense onto surfaces in the enclosure to sterilise such surfaces; wherein means are provided for monitoring gas temperature and for monitoring the condensation of the decontaminant gas in the enclosure and means are provided for controlling the dispensing of the decontaminant gas/water vapour into the gas in the preparation region in response to the levels determined by said monitoring to provide a predetermined level of condensation of the decontaminant gas/water vapour in the enclosure.

8. An apparatus as claimed in claim 7, wherein means are provided for circling air through the preparation region enclosure and to convey the decontaminant

gas/water vapour mixture to the enclosure.

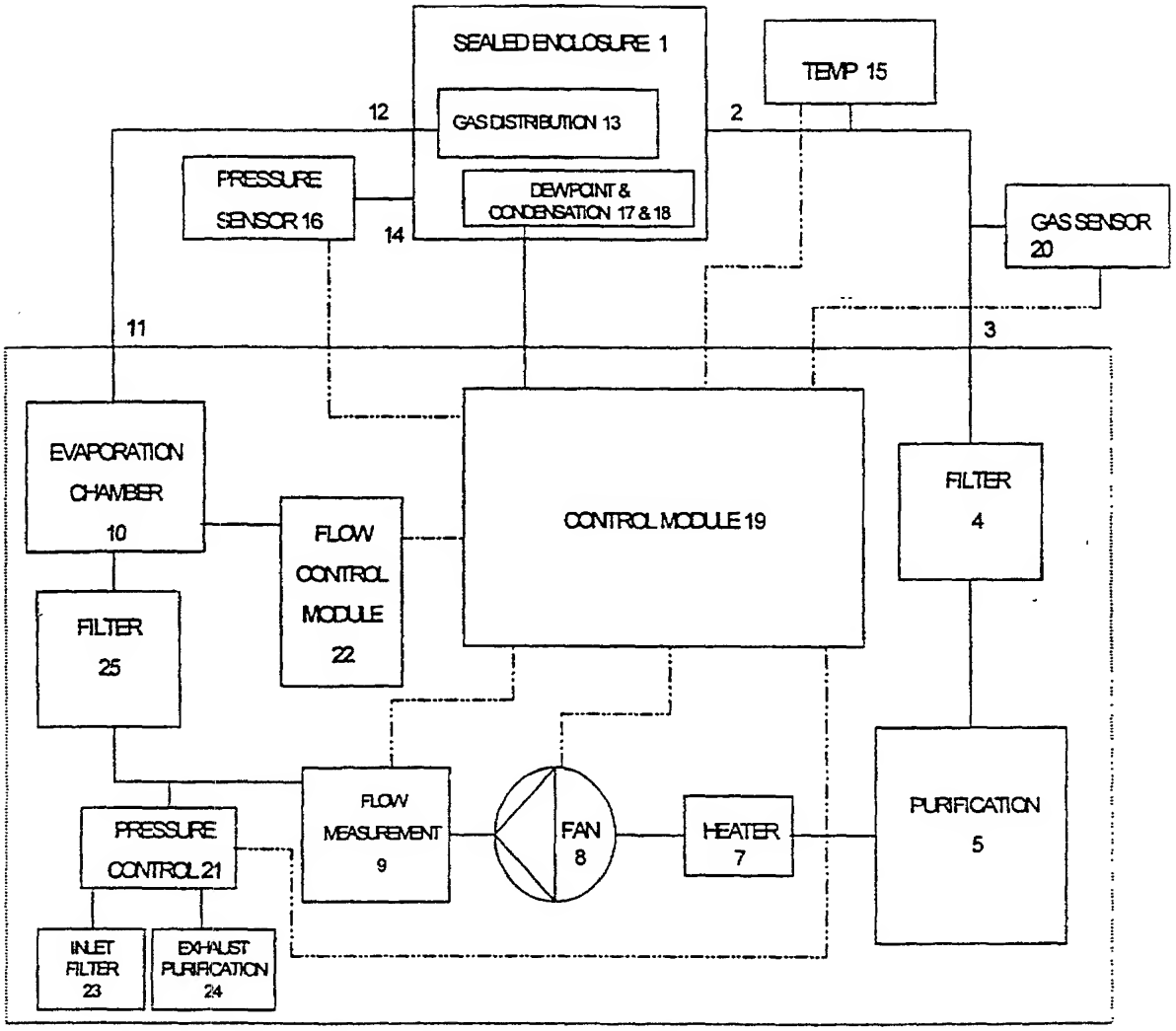
9. An apparatus as claimed in claim 7 or claim 8, wherein means are provided for filtering the gas 7 in said preparation region prior to circulation through the enclosure.

10. An apparatus as claimed in any of claims 7 to 9, wherein means are provided to monitor the gas pressure in the enclosure and means are provided to adjust the gas pressure therein by controlling the supply of gas circulating through the enclosure.

11. An apparatus as claimed in any of the preceding claims, wherein after a sufficient amount of decontaminant gas has been condensed in the chamber to achieve decontamination, means are provided for formulating supply of the decontaminant gas and water vapour mixture to the preparation region after a sufficient amount of decontaminant gas has been condensed in the chamber to achieve decontamination and for removing the decontaminant gas from the sealed enclosure.

12. An apparatus as claimed in claim 11, wherein the means for removing the decontaminant gas from the sealed enclosure comprises means for passing clean filtered gas through the enclosure and releasing the gas exiting the enclosure to atmosphere, or means for circulating the gas exiting the enclosure through an auxiliary circuit containing a catalytic decomposition device or absorption device for the decontaminant gas to remove the decontaminant gas.

Fig 1


SEALED ENCLOSURE 1
TEMP 15
12
GAS DISTRIBUTION 13
2
PRESSURE SENSOR 16
DEWPOINT & CONDENSATION 17 & 18
14
GAS SENSOR 20
11
3
EVAPORATION CHAMBER 10
CONTROL MODULE 19
FILTER 4
FLOW CONTROL MODULE 22
FILTER 25
FLOW MEASUREMENT 9
FAN 8
HEATER 7
PURIFICATION 5
PRESSURE CONTROL 21
INLET FILTER 23
EXHAUST PURIFICATION 24

COMBINED DECLARATION and POWER OF ATTORNEY
(Utility, Design, National Stage of PCT)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

(Check one applicable item below)

[ ] utility patent application
[ ] design patent application
[x] national stage of PCT patent application

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (*if only one name is listed below*) or an original, first and joint inventor (*if plural names are listed below*) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION[2]

SEALED ENCLOSURE STERILIZATION

SPECIFICATION IDENTIFICATION

the specification of which:

(*complete (a), (b), or (c)*)

(a) [ ] is attached hereto.

(b) [ ] was previously filed _____, as United States Patent Application Serial No. _____.

(c) [x] was described and claimed in PCT International Application No. PCT/GB00/02137 filed on June 2, 2000 and as amended under PCT Article § 19 on _____ (*if any*).

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claim(s), as amended by any amendment specifically referred to in the declaration, referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56.

FOREIGN PRIORITY CLAIM
(35 USC § 119(a)-(d))

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))[3]

(d) [ ] no such applications have been filed.
(e) [x] such applications have been filed as follows.

Note: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below, and make the priority claim.

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS [4] (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, **month**, year)	PRIORITY CLAIMED UNDER § 119 or § 365
PCT	PCT/GB00/02137	2 June 2000	[x] YES NO [ ]
Great Britain	GB 9913082.5	4 June 1999	[x] YES NO [ ]
			[ ] YES NO [ ]
			[ ] YES NO [ ]

U.S. PRIORITY CLAIM
(35 USC § 120)

I hereby claim the benefit under 35 USC § 120 of any United States application(s) or § 365(c) of any PCT international application designating the United States of America listed below, if any, and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of title 35 USC § 112, I acknowledge duty to disclose information which is material to patentability as defined in title 37, Code of Federal Regulations § 1.56 which became available between the filing date of the prior application and the national or PCT international application filing date of this application.

UNITED STATES or PCT PARENT APPLICATION NO.	PARENT FILING DATE (month, day, year)	PARENT PATENT NO. (if applicable)

POWER OF ATTORNEY

I hereby appoint as my attorneys and/or patent agents all attorneys and/or patent agents listed under the following Customer Number, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

022913

PATENT TRADEMARK OFFICE

** Customer Number Label **

All correspondence and telephonic communications should be directed to:

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)[5]

NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents

Full name of sole or first inventor

1-DD DAVID | | WATLING

(*GIVEN NAME*) (*MIDDLE INITIAL OR NAME*) *FAMILY (OR LAST NAME)*

Inventor's signature x [signature]

Date x 10TH DEC 2001 x Country of Citizenship UNITED KINGDOM GBX

Residence HEATHCREST, GUILDFORD ROAD, WESTCOTT, SURREY, RH4 3LB, UNITED KINGDOM

Post Office Address - same as above -

Full name of second joint inventor, if any

(*GIVEN NAME*) (*MIDDLE INITIAL OR NAME*) *FAMILY (OR LAST NAME)*

Inventor's signature

Date Country of Citizenship

Residence

Post Office Address